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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/776,521 | 02/12/2004 | Jessica Baker Flechtner | 8449-405-999 | 4151 |

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222 EAST 41ST ST
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EXAMINER

TIDWELL, JUDY LILLE

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| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED: 02/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---|--|
| Office Action Summary | Application No. 10/776,521 | Applicant(s) FLECHTNER ET AL. | |
| | Examiner Judy Lille Tidwell, PhD | Art Unit 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, 11-13, drawn to a hybrid antigen comprising at least one antigenic domain of an infectious agent or tumor antigen and a binding domain that non-covalently binds to a heat shock protein, classified in class 530, subclass 350.
- II. Claims 5-7, 14-16, drawn to a method for inducing an immune response to an infectious agent or tumor antigen, comprising administering a hybrid antigen and heat shock protein, classified in class 514, subclass 2.
- III. Claims 8-10, 17-19, partially drawn to a method for treating an infectious disease comprising administering a hybrid antigen and heat shock protein, classified in class 514, subclass 2.
- IV. Claims 8-10, 17-19, partially drawn to a method for treating cancer comprising administering a hybrid antigen and heat shock protein, classified in class 514, subclass 2.
- V. Claim 20, drawn to a peptide that is Asn Leu Leu Arg Leu Thr Gly Trp (SEQ ID NO: 417), Phe Tyr Gln Leu Ala Leu Tyr Trp (SEQ ID NO: 418), or Arg Lys Leu Phe Phe Asn Leu Arg Trp (SEQ ID NO: 419), classified in class 530, subclass 300.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are structurally and functionally distinct.

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While the inventions of Groups I and V are polypeptides, in this instance the polypeptide of Group V is a single peptide linker sequence, whereas Group I is a stress hybrid antigen complex further comprising at least one antigenic domain of an infectious agent or tumor antigen, at least one binding domain that non-covalently binds to a heat shock protein, and a peptide linker there between. Thus, the compositions of Groups I and V are structurally distinct molecules; any relationship between compositions of Groups I and V is dependent upon the correlation between the scope of the polypeptides that make up the complexes.

Furthermore, searching the inventions of Groups I and V would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications.

Inventions II-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the specification does not disclose that the methods of the different inventions would be used together.

In the instant case the different inventions are drawn to a method for inducing an immune response to an infectious agent or tumor antigen in Group II, a method for treating an infectious disease in Group III, and a method for treating cancer in Group IV. The different inventions comprise distinct active steps and different effects which demonstrates that each method has a different mode of operation.

Each invention performs a function using a structurally and functionally divergent material. For example, an antibody to detect the immune response for Group II would be a distinct and different step than monitoring the response of an infectious disease from treatment in Group III or monitoring the response of a tumor from treatment in Group IV. Moreover, the methodology and materials necessary for whether the effect set forth in the preamble of each of the different inventions (i.e. treating and inducing an immune response) differ significantly for each of the materials. Therefore, each method

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is divergent in materials and steps and would require separate and distinct searches. For these reasons the inventions in Groups II-IV are patentably distinct.

Inventions I and II-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of Groups II, III, and IV.

Searching the inventions of Groups I-V together would impose serious search burden. The inventions of Groups I-V have a separate status in the art as shown by their different classifications. Additionally, in the instant case, the search for the complexes and the method of using the complexes are not coextensive. Groups I and V encompass molecules that are claimed in terms of amino acid sequence and protein complex, which are not solely required for the search of Group II-IV. In contrast, the search for Groups II-IV would require a text search for the method of treating an infectious disease, cancer, or inducing an immune response in addition to an amino acid search of the protein complexes. Moreover, even if the compositions were known, the method of using the products may be novel and unobvious in view of the preamble or active steps.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each Group is not required for the other Groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Groups I and V, are generic to a plurality of disclosed patentably distinct species comprising the following peptide linkers: Asn Leu Leu Arg Leu Thr Gly Trp (SEQ ID NO: 417), Phe Tyr Gln Leu Ala Leu Tyr Trp (SEQ ID NO: 418), or Arg Lys Leu Phe Phe Asn Leu Arg Trp (SEQ ID NO: 419) which differ at least in structure such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

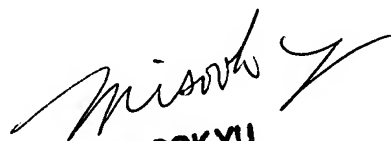
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Judy Lille Tidwell, PhD whose telephone number is 571-272-5952. The examiner can normally be reached on 8:00AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JLT


MISOOK YU
PATENT EXAMINER